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New Study Demonstrates That Prostate-Specific Membrane Antigen (PSMA) Expression Predicts Prostate Cancer Recurrence

PRINCETON, N.J., May 22 /PRNewswire-FirstCall/ -- Cytogen Corporation today announced the presentation of clinical data demonstrating that a high level of prostate-specific membrane antigen (PSMA) in prostate tissue is a strong predictor of prostate cancer recurrence. The data was presented at the 101st American Urological Association Annual Meeting held May 20-25, 2006, in Atlanta, GA.

In the study, independent investigators from Ulm, Germany, and Boston, MA, analyzed PSMA expression by tissue microarray in 96 patients with either localized or metastatic prostate cancer who had undergone radical prostatectomy, or surgical removal of the prostate, as monotherapy. One third of the patients had disease confined to the prostate gland with no spread to lymph nodes (LN), 33% had only one positive LN, and the remaining third had more than one positive LN. Following therapy, patients were monitored for a maximum of 12.6 years with an average follow-up of 2.7 years.

Significant up-regulation of PSMA expression was noted in patients with metastatic disease as compared to those with localized prostate cancer and in localized disease compared to benign prostate tissue ($p<0.05$). High PSMA levels were associated with a significant increase in disease recurrence following therapy ($p<0.001$) in univariate statistical analyses. Other significant parameters for predicting disease recurrence included LN positivity, extraprostatic extension of disease, seminal vesicle invasion by disease, and Gleason score 8-10. Using multivariate statistical analyses, the best model to predict disease recurrence included high PSMA expression ($p<0.01$) and extraprostatic extension ($p=0.02$) after adjusting for Gleason score and seminal vesicle invasion.

"We are very encouraged by the findings of this new study, which validate and extend upon data previously published demonstrating that over-expression of PSMA in primary prostate cancer not only correlates with other adverse traditional prognostic factors, but can independently predict both a higher incidence and shorter time to disease recurrence," said Michael D. Becker, president and chief executive officer of Cytogen. "There is a tremendous need for better prognostic markers in prostate cancer to assist in the identification of patients with aggressive forms of the disease who can potentially benefit from earlier and more intensive forms of treatment. The findings presented at AUA further support our belief in the importance of PSMA as an independent prostate cancer marker and important diagnostic and therapeutic target."

A copy of the following abstract presented at the AUA annual meeting is currently available on the AUA website at http://www.auanet.org/, which is not part of this press release:

"Prostate-Specific Membrane Antigen (PSMA) Expression as a Predictor of Prostate Cancer Progression" presented on Sunday, May 21 from 1:00 p.m. to 3:00 p.m. during a Podium Session on Prostate Cancer: Detection and Screening (I) (Abstract # 479).

About Prostate Cancer

Prostate cancer is the most common type of cancer found in American men, other than skin cancer. In 2006, the American Cancer Society estimates that there will be about 234,000 new cases of prostate cancer in the United States and that about 27,000 men will die from the disease. It is estimated that there are more than 2 million American men currently living with prostate cancer. Tests to determine the amount of prostate-specific antigen (PSA), a protein produced by the cells of the prostate gland, in the blood along with a digital rectal exam is used to help initially detect prostate cancer and is also used to monitor patients with a history of prostate cancer to see if the cancer has come back, or recurred. PSA levels cannot directly identify the extent or location of disease.

About PROSTASCINT

Cytogen's PROSTASCINT molecular imaging agent is the first and only commercial product targeting PSMA. PROSTASCINT consists of a monoclonal antibody (7E11.C5.3) directed against PSMA that is linked to the imaging radioisotope Indium-111. By targeting PSMA, the PROSTASCINT molecular imaging procedure can detect the extent and spread of prostate cancer using a standard gamma camera.

Cytogen is also developing CYT-500, a therapeutic product candidate using the same monoclonal antibody from PROSTASCINT combined with a higher affinity linker to attach a therapeutic as opposed to an imaging radionuclide. CYT-500 is designed to enable targeted delivery of a cytotoxic agent to PSMA- expressing cells. Cytogen expects to begin the first U.S. Phase I clinical trial of CYT-500 in patients with hormone-refractory prostate cancer during 2006.

PROSTASCINT is indicated as a diagnostic imaging agent in newly diagnosed patients with biopsy-proven prostate cancer, thought to be clinically localized after standard diagnostic evaluation and who are thought to be at high risk for pelvic lymph node metastases. PROSTASCINT is also indicated as a diagnostic imaging agent in post-prostatectomy patients with a rising PSA and a negative or equivocal standard metastatic evaluation in whom there is a high clinical suspicion of occult metastatic disease.

A copy of the full prescribing information for PROSTASCINT, including warnings, precautions, adverse events and other safety information, may be obtained in the U.S. from Cytogen Corporation by calling toll-free 800-833- 3533 or by visiting the Web site at http://www.cytogen.com/, which is not part of this press release.

About PSMA

PSMA is a protein abundantly expressed on the surface of prostate cancer cells, with an increased expression in high-grade cancers, metastatic disease and hormone-refractory prostate cancer. PSMA is also present at high levels on the newly formed blood vessels, or neovasculature, needed for the growth and survival of many solid tumors. In contrast to other prostate-related antigens such as prostate-specific antigen (PSA), prostatic acid phosphatase (PAP) and prostate secretory protein, PSMA is a membrane glycoprotein that is not secreted. These unique attributes make PSMA an excellent target for monoclonal antibody diagnostic and therapeutic options in prostate and potentially other cancers. Clinical studies have also demonstrated that overexpression of PSMA determined by immunohistochemical staining using the 7E11.C5.3 antibody in primary prostate cancer not only correlates with other adverse traditional prognostic factors, but can independently predict disease recurrence.

ABOUT CYTOGEN CORPORATION

Founded in 1980, Cytogen Corporation of Princeton, NJ, is a biopharmaceutical company dedicated to improving the lives of patients with cancer by acquiring, developing and commercializing innovative molecules targeting the sites and stages of cancer progression.

Cytogen's marketed products include QUADRAMET(R) (samarium Sm-153 lexidronam injection), PROSTASCINT(R) (capromab pendetide) kit for the preparation of Indium In-111 capromab pendetide, and SOLTAMOX(TM) (tamoxifen citrate, oral solution 10mg/5mL) in the United States. Cytogen's development pipeline consists of CYT-500, a therapeutic radiolabeled antibody targeting prostate-specific membrane antigen (PSMA), a protein highly expressed on the surface of prostate cancer cells and the neovasculature of solid tumors. Cytogen also has exclusive United States marketing rights to COMBIDEX(R) (ferumoxtran-10) for all applications, and the exclusive right to market and sell ferumoxytol (previously Code 7228) for oncology applications in the United States. Full prescribing information for the Company's products is available at http://www.cytogen.com/ or by calling 800-833-3533. For more information, please visit the Company's website at http://www.cytogen.com/, which is not part of this press release.

This press release contains certain "forward-looking" statements within the meaning of the Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended. All statements, other than statements of historical facts, included in this press release regarding our strategy, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management are forward-looking statements. Such forward-looking statements involve a number of risks and uncertainties and investors are cautioned not to put any undue reliance on any forward-looking statement. There are a number of important factors that could cause Cytogen's results to differ materially from those indicated by such forward-looking statements. In particular, Cytogen's business is subject to a number of significant risks, which include, but are not limited to: the risk of obtaining additional capital; the risk of obtaining the necessary regulatory approvals; the risk of whether products result from development activities; the risk of shifts in the regulatory environment affecting sales of Cytogen's products such as third-party payor reimbursement issues; the risk associated with Cytogen's dependence on its partners for development of certain projects, as well as other factors expressed from time to time in Cytogen's periodic filings with the Securities and Exchange Commission (the "SEC"). As a result, this press release should be read in conjunction with Cytogen's periodic filings with the SEC. The forward-looking statements contained herein are made only as of the date of this press release, and Cytogen undertakes no obligation to publicly update such forward-looking statements to reflect subsequent events or circumstances.

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